

JUN 03 2004

K040944

510(k) Summary – ResControl™ II

Date Prepared	30 th March, 2004
Official Contact	Dr Lionel King V.P., Regulatory Affairs ResMed Ltd 97 Waterloo Road North Ryde, NSW 2113 Australia Tel: +61 (2) 9886 5000 Fax: +61 (2) 9878 5517
Classification Reference	21 CFR 868.5905
Product Code	BZD
Common/Usual Name	CPAP System / Non continuous Ventilator (with accessory)
Proprietary Name	ResControl™ II
Predicate Device(s)	ResMed UCU (K961783)
Reason for submission	New Device
Indications for Use	The ResControl II is intended to be used by clinicians with ResMed flow generators that have software incorporating ResMed's proprietary communication protocol. ResControl II displays data, relays data to a polysomnograph and acts as a manometer. ResControl II also provides functionality for setting flow generator parameters.

Substantial Equivalence

The new device has the following similarities to the previously cleared predicate device.

Same intended use

Similar operating principle

Similar technologies

Same manufacturing process

Design and Verification activities were performed on the ResControl II as a result of the risk analysis and product requirements. All tests confirmed the product met the acceptance criteria. ResMed has determined that the new device is Substantially Equivalent to the predicate device. ResControl II has not altered the safety and effectiveness when used in treatment studies for Chronic Obstructive Pulmonary Disease (COPD) or Obstructive Sleep Apnea (OSA) in adult patients. The new device complies with the applicable standards and requirements referenced in the FDA guidance documents:

- FDA Reviewer Guidance for Premarket Notifications, November 1993.
- FDA Draft Reviewer Guidance for Ventilators (July 1995)
- FDA reviewer's and industry, Guidance for the content of premarket submissions for software contained in medical devices, May 1998.

Intended Use

The ResControl II is intended to be used by clinicians with ResMed flow generators that have software incorporating ResMed's proprietary communication protocol. ResControl II displays data, relays data to a polysomnograph and acts as a manometer. ResControl II also provides functionality for setting flow generator parameters.

Device Description

The performance and functional characteristics of the ResControl II system includes all the user friendly features of the predicate device, UCU. ResControl II is designed to transfer data from a CPAP or bilevel Flow Generator to a polysomnograph display system such as Somnologica (K971813). ResControl II also provides parameter setting of Flow Generators within the hospital or sleep lab facilities.



Dr Lionel King
V.P., Regulatory Affairs
ResMed.

30th March, 2004



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Resmed Limited
c/o David D'Cruz
Resmed Corporation
14040 Danielson St.
Poway, CA 92064-6857

JUN 03 2004

Re: K040944
Trade/Device Name: ResControl II
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator
Regulatory Class: II
Product Code: BZD
Dated: April 4, 2004
Received: April 12, 2004

Dear Mr. D'Cruz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – David D'Cruz

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Chiu Lin', with a stylized flourish at the end.

Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indication for Use

510(k) Number (if known):

K040944

Device Name:

ResControl II

Indications for Use:

The ResControl II is intended to be used by clinicians with ResMed flow generators that have software incorporating ResMed's proprietary communication protocol. ResControl II displays data, relays data to a polysomnograph and acts as a manometer. ResControl II also provides functionality for setting flow generator parameters.

Prescription Use X

AND/OR


Over-The-Counter Use

(Part 21 CFR 801 Subpart D)

(Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of Device Evaluation (ODE)



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(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number:

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